

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Donohoe, Brendan M.; et. al.
Assignee: Cardica, Inc.
Title: Method and Apparatus for Creating an Opening in the Wall of a Tubular Vessel
Serial No.: 10/054,745 Filing Date: January 22, 2002
Examiner: Vy Q. Bui Group Art Unit: 3731
Docket No.: 057

March 23, 2007

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 CFR §41.41 AND MPEP 1208(I)

This Reply Brief is prepared and submitted in response to the Examiner's Answer mailed on February 5, 2007.

I. **STATUS OF CLAIMS**

Claims 1-15, 17-31, 33-39 and 51 stand finally rejected. Claims 32 and 40-50 have been objected to. These claims are set forth in the appendix attached hereto.

Claims 16 and 52-61 have been withdrawn. These claims are not at issue and are not set forth in the appendix attached hereto.

II. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-15

Independent claim 1 stands finally rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,825,362 to Hougen (“Hougen”). Dependent claims 5-6 and 8-14 also stand rejected under Hougen. Independent claim 1 also stands finally rejected under 35 U.S.C. §102(b) as being anticipated by the St. Jude Medical Instructions for Use.” Dependent claims 7 and 15 also stand finally rejected under that reference.

B. Claims 17-31, 33-39 and 51

Independent claim 17 and dependent claims 18-31, 33-39 and 51 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Hougen.

III. ARGUMENTS

A. Claims 1-15

As claimed in claim 1, both the piercing member and the cutter “translate together to penetrate the wall of the vessel.” As set forth in the specification, the phrase “translate together” means that the piercing member and the cutter are “fixed...with respect to translation” to penetrate the wall of the vessel.¹

U.S. Pat. No. 3,825,362 to Hougen (“Hougen”) describes a pointed pilot pin 42 coaxial with an annular hole cutter 14.² The Office Action analogizes the pilot pin 42 of Hougen to the claimed piercing member, and analogizes the cutter 14 of Hougen to the claimed cutter.³ As the tool of Hougen is actuated, the “pilot pin 42 progressively retracts as cutter 14 advances into the workpiece.”⁴ That is, the pilot pin 42 and the cutter 14 of Hougen do not “translate together to penetrated the wall of the vessel” as required by claim 1, but instead translate in opposite directions to cut a hole in the workpiece. To interpret the phrase “translate together” to include “translation in opposite directions” would vitiate the claim limitation “together” in violation of the MPEP, which requires that “all words in a claim must be considered in judging the patentability of that claim against the prior art.”⁵

Further, claim 1 requires that the piercing member and the cutter “translate together to penetrate the wall of the vessel.” The Answer points to Figure 2 of Hougen in support of the rejection of claim 1, and states that “during a translation movement of Hougen device before contacting wall 12, cutter 12 [sic] and auger/spike/piercing member 42 are axially fixed to one another because there is substantially no relative motion between cutter 14 and

¹ *Id.*; page 3, lines 21-22.

² Hougen; *e.g.*, col. 2, lines 36-37, 59-62; Figures 2-4, 6-15.

³ Final Action, page 2.

⁴ Hougen; col. 4, lines 1-2; *e.g.*, Figures 2-3, 12-14. (emphasis added).

auger/spike/piercing member 42.”⁶ Figure 2 of Hougen shows the tool of Hougen spaced apart from the workpiece 12, before contacting and cutting the workpiece 12. However, any relative motion, or lack thereof, of components of the tool of Hougen before penetration of a workpiece is irrelevant to claim 1, which requires that the piercing member and the cutter “translate together to penetrate the wall of the vessel.”

Next, at no time during prosecution of this application has the Patent Office contended that the St. Jude Medical Instructions for Use disclose the claimed piercing member and cutter that “translate together to penetrate the wall of the vessel.” The Final Action of May 18, 2006 states in regard to that reference, *in toto*, that “Figs. 14 and 15 of ‘St. Jude Medical, Instruction for Use’ shows a device as recited in the claims including a cutter beveled outward and a needle/barb/spike having a width at the proximal end greater than the width of the needle shaft.” Turning to the Answer, it simply states in regard to that reference, *in toto*, that “[a]s to the reference of ‘St. Jude Medical Instruction for Use,’ a similar rationale is applicable to the Applicants’ arguments.” Neither of these rejections contend or even suggest that the St. Jude Medical Instructions for Use describe a piercing member and cutter that “translate together to penetrate the wall of the vessel.” Based on this record alone, claim 1 should be allowed over the St. Jude Medical Instructions for Use.

The St. Jude Medical Instructions for Use discloses a needle positioned within a cutter blade, where that needle is movable in translation relative to the cutter blade.⁷ The user is directed to “[r]otate the cutter blade to advance through the aorta until the hole is complete.”⁸

⁵ MPEP 2143.03 (*quoting In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1974)).

⁶ Examiner’s Answer; page 6. (emphasis added).

⁷ St. Jude Medical Instructions for Use; page 7; Figures 13-15.

⁸ *Id.*, page 7; Figure 15.

The cutter blade advances while the needle is substantially stationary.⁹ Thus, the needle and cutter blade translate relative to one another to penetrate the wall of the target vessel, and therefore do not “translate together to penetrate the wall of the vessel.”

Thus, neither Hougen nor the St. Jude Medical Instructions for Use expressly or inherently describes each and every element claimed in claim 1, as required for anticipation under MPEP 2131, and as a result claim 1 is believed to be in condition for allowance. Claim 1 was acknowledged as generic in the Office Action of August 24, 2005, so allowance of generic claim 1 would be as to all species. Claims 2-15 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 10, the Examiner’s Answer states a conclusion, with no citation to the drawings or specification of Hougen and no analysis, that “the cutter can be considered as a cap or plug being substantially hemostatic.”¹⁰ This statement is an improper inherency rejection, because it is unsupported contrary to the requirements of the MPEP: “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”¹¹ The device of Hougen is a “machine tool”¹², and the Answer provides no analysis of how using a machine tool to cut tissue would result in anything other than an industrial accident, much less any analysis of how the jagged-edged cutter 14 of that machine tool could be “substantially hemostatic.”

⁹ *Id.*

¹⁰ Examiner’s Answer, page 7.

¹¹ MPEP 2112 (*citing Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)) (emphasis in original).

¹² Hougen; col. 1, lines 63-65; col. 2, lines 50-51.

B. Claims 17-31, 33-39 and 51

Claim 17 is directed to a surgical tool for removing tissue from the wall of a vessel to create an opening, where that tool comprises, among other elements, “a rotatable cutter [and] an auger assembly fixed to and substantially coaxial with said cutter.” The auger assembly includes an auger at its distal end. Because the claimed auger assembly is “fixed to” the cutter, it is necessarily fixed to the cutter in translation and rotation: “Because the auger and the cutter are fixed to one another, they rotate and advance together to penetrate the wall of a tubular vessel and cut tissue from it.”¹³

The standard usage of the term “fixed” is “firmly placed or attached, not movable.”¹⁴ As set forth above, the pilot pin 42 and the cutter 14 of Hougen move in opposite translational directions to cut a hole in the workpiece, such that the pilot pin 42 is movable relative to the cutter 14. Thus, the pilot pin 42 and the cutter 14 are not and cannot be fixed to one another. The Answer contends that the cutter 14 and pilot pin 42 are “axially fixed to each other because there is substantially no relative motion” between them.¹⁵ However, the lack of relative motion at a particular time between the cutter 14 and pilot pin 42 does not imply that the two are “not movable”, and therefore fixed, relative to one another. Indeed, Hougen moves the cutter 14 and the pilot pin 42 in opposite directions to cut a hole in the workpiece – a feat Hougen could only accomplish if the cutter 14 and the pilot pin 42 were not fixed (*i.e.*, were movable) relative to each other.

None of the references expressly or inherently describes each and every element claimed in claim 17, and as a result claim 17 is believed to be in condition for allowance.

¹³ Specification; page 3, lines 14-16.

¹⁴ WEBSTER'S NEW WORLD DICTIONARY, SECOND COLLEGE EDITION 528 (1978).

¹⁵ Examiner's Answer, page 6.

Claims 18-31, 33-39 and 51 depend from claim 17, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 38, that Hougen does not describe “an impulse source configured to rotate and translate said auger and said cutter.” The terms “impulse” and “impulse source” are expressly defined in the Specification, under MPEP 2111.01(IV):

A force that acts on a body for a short time but produces a large change in its linear or angular momentum is called an impulsive force. As used in this document, the term “impulse source” refers to a source of such an impulsive force.¹⁶

That is, the claimed “impulse source” is the source of a force that acts on a body for a short time but produces a large change in its linear or angular momentum. Turning to claim 38, that “body” is “said auger and said cutter.” The Answer states that “spindle 40 of a machine such as a press drill [provides] impulse source.”¹⁷ However, Hougen merely states that a spindle 40 is a rotary driven member,¹⁸ and describes nothing about the claimed “impulse source”; that is, nothing about a source of a force that acts on the auger and cutter for a short time but produces a large change in their linear or angular momentum.

¹⁶ Specification; page 15, lines 22-25.

¹⁷ Examiner’s Answer, page 7.

¹⁸ Hougen; col. 2, lines 55-59.

VII. CONCLUSION

For the above reasons, Applicants respectfully submit that the rejection of pending claims 1-15, 17-31, 33-39 and 51 was unfounded. Accordingly, Applicants request that the rejection of those claims be reversed and that those claims be allowed.

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EVIDENCE APPENDIX

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